APR 0 9 2013

K123916 510(k) Summary

Submitter:	Osypka Medical, Inc. 7463 Draper Avenue, La Jolla, CA 92037
Contact Person:	Markus Osypka, Ph.D., President Osypka Medical, Inc. 7463 Draper Avenue, La Jolla, CA 92037
Device Trade Name:	PSA™ Series, PSA 200™ and PSA 100™ Pacing System Analyzer
Predicate Device:	Biotronik ERA 300 Dual Chamber Pacing System Analyzer (K964190)
Device Description:	PSA™ Series devices are portable pacing system analyzers, which are intended to be used for the evaluation of the integrity and most beneficial placement of stimulation leads. The integrity of a stimulation lead system is characterized by its electrical impedance, the measurement results of which shall meet the specifications of the manufacturer of the lead system. The most beneficial placement of a stimulation lead system is determined by the ability of the PSA Series device to capture the heart rhythm (successful stimulation) and to measure reasonable high amplitudes of P and/or R waves and corresponding slew rates. The PSA™ Series encompasses a single-channel device (PSA 100) and dual-channel device (PSA 200) with each channel employing a differential stimulation output and a differential sensing input. Stimulation leads or extension cables are connected to patented receptacles accommodating pins of 0.9 ... 2 mm or Hypertronics™ style sockets. In addition to the aforementioned intra-cardiac channels, a PSA Series device offers an additional channel and corresponding terminal for a 5-lead surface ECG.

Device Description (continued):	The user interface is divided into a touch screen and an array of four keys dedicated to the functions • On / Off — Turn device on or off • Emergency — Switch to emergency stimulation mode • High-Rate — Switch to High-Rate stimulation mode • Home — Return to main menu The user monitors device measurements, heart activity and device status through the touch screen and LED indicators. Functions provided by PSA™ series pacing system analyzers are organized into so called applications such as (availability depending on PSA Series model): • 1/A — Single-chamber stimulation (Channel 1/A) • 2/RV — Single-chamber stimulation (Channel 2/RV) • DDD — Atrioventricular (dual-chamber) stimulation • UHS — Burst stimulation (Universal Heart Stimulator) By choosing one application, the (touch) screen displays all functions and information relevant to the specific application. The screen displays with minimal delay a marker signal and up to four signal waveforms all of which a user can select from the group of up to three IEGM signal waveforms (1/A, 2/RV; availability depending on PSA model) and seven surface ECG standard vectors (I, II, III, aVR, aVL, aVF, V). The device provides or facilitates the following measurements: • Sensing of intrinsic events of the heart: • P/R wave amplitudes and slew rate • Rates (PP, RR interval) • Intrinsic AV delay (antegrade conduction time) • Retrograde conduction time • Wenckebach point (2:1 conduction) • Stimulation of the heart • Capture threshold in up to 2 chambers • Lead impedances • Burst stimulation During an implantation procedure a PSA™ Series device can temporarily take over the functions of a cardiac pacemaker. Measurement results can be stored to a virtual print-out page, which upon completion of all measurements is transmitted wirelessly to a separate printer or computer. User-configurable settings for general use of the device and individual applications are stored in non-volatile memory.

Device Description (continued):	The HIGH-RATE function (dedicated key below the touch screen) provides bust stimulation at rates variable from 70 to 1,000 ppm for terminating atrial and ventricular tachycardia. The (optional) UHS application is special form of the high rate function. Within the UHS application, the user can program a train of burst prior to clinical application, which is also referred to as programmable electrical stimulation (PES). Pressing the EMERGENCY key (dedicated key below the touch screen) immediately initiates an emergency stimulation (VVI, 60 ppm, 7.5 V, 1.0 ms). Pressing the HOME key allows the user to return to the home screen (main menu). The device can operate from line power or the integrated rechargeable battery which provides up to 4 hours of continuous operation. A medical-grade AC power supply is part of the delivery unit. An integrated backup battery maintains stimulation in the unlikely event of a failure of the integrated rechargeable battery or AC power. The robust device enclosure is protected against accidental fluid spill.
Intended Use:	This device is indicated for use in stimulation lead system analysis prior or during implantation of an electrical stimulator (pacemaker, pulse generator), for emergency stimulation and for high-rate (burst) stimulation limited to temporary diagnostic and therapeutic application.
Performance Test- Bench:	Purpose of bench testing is to verify the performance of the device under test with respect to employing the intended stimulation (pacing) mode (including high-rate and emergency modes), stimulation (pacing), sensing and timing parameters, the ability of the device to detect faulty conditions, and with respect to the predicate device. **Stimulation Modes** Bench testing using an Interstim II heart simulator verified that the device under test performed the following stimulation modes as intended: AAI, VVI, DDD, VDD, DDI and VDI. Bench testing further verify that the functions high rate pacing and emergency pacing perform as intended. **Stimulation, Sensing and Timing Parameters** Parameters were measured with the Osypka SMS 1000, a custom-build computer-assisted test system that consists of the PC card EKG2GEN (a specialized and combined ADC/DAC card) and the PC program PACE. It is part of the supervised measuring equipment of the company and used for final measurements of external pacemakers and pacing system analyzers. The test system fulfills the requirements of the applicable standards for measuring pacemaker parameters and is used otherwise in the production process of pacemakers.

	Parameter	Bench Testing
Stimulation Parameters	Pulse Amplitude	Verification for pulse amplitude of 0.1...10 V for each stimulation channel 1/A, 2/RV
	Pulse Width	Verification for pulse widths of 0.1...2.5 ms for each stimulation channel 1/A, 2/RV
	Pulse Rate	Verification for pulse rates of 30...220 ppm for each stimulation channel 1/A, 2/RV
	Sensitivity	Verification for sensitivity threshold of 0.2...20 mV for each sensing channel 1/A, 2/RV
Timing	AV Delay	Verification for AV Delay settings of 10...400 ms measured between channel 1/A and 2/RV
	Refractory Periods	Verification for refractory period settings of 250...500 ms for each channel 1/A, 2/RV

Test of Device Behavior Under Fault Conditions

The device under test was exposed to the following device and application related faults and reacted as intended:

- Start-up self-test failed
- Electrode impedance to low (short circuit)
- Electrode impedance to high (open lead)
- EGM signal noise
- Battery low
- Battery empty
- Attempt to switch device off during stimulation
- High Rate pacing timeout atrium

Essential Performance Comparison Testing

The device under test was compared to its predicate device with respect to the following parameters:

- Heart Rate / RR Interval
- P/R Wave Amplitude
- Lead Impedance
- Retrograde Conduction Time
- Wenckebach Point

The test results demonstrated a substantial equivalence between the device under test and the predicate device.

Performance Test-Clinical	**Performance Test – Clinical** The objective of this clinical investigation is to determine whether Osypka Medical's PSA pacing system analyzer (referred to hence forth as the "PSA") is safe and effective within the scope of its intended use. This objective will be met by the following clinical investigations conducted at two clinical sites in Hamburg, Germany. The clinical investigations were conducted during routine pacemaker implantation procedure in the operating room: **Intrinsic measurement comparisons** **Method** PSA's measurements of the patient's intrinsic values will be compared to the Biotronik's ERA 300 dual chamber pacing system analyzer (referred to hence forth as the "ERA") and Medtronic Carelink 2290 Analyzer (referred to hence forth as the "M2290") performed on the same patient in consecutive order where these measurements are appropriate. PSA, ERA, and M2290 parameters analyzed include heart rate (PP/RR intervals), amplitude, slew rate, impedance, anterograde conductance (AV time) and retrograde conductance (VA time). Data from 17 patients were used in this analysis. Although the M2290 is not used as a predicate device, it serves as a reference when differences between the PSA and ERA need further explanation. **Results** Acceptance criteria were established for each parameter compared across devices. Based on the data analyzed from 17 patients (15 atriums and 18 ventricles), the PSA fulfilled the acceptance criteria for each parameter and thus can be considered equivalent to the ERA. **Stimulation and Sensing Evaluation** **Method** ECG tracing are analyzed beat by beat while the PSA paces in order to determine effective sensing and pacing. Effective sensing is defined here as inhibition of the atrial and/or ventricle pacemaker stimulus in the presence of P waves and R waves, respectively. Effective pacing is defined here as effective atrial and/or ventricle stimulation with their respective time domains. ECG tracings and physician notes will be used to determine whether an adverse event occurred while the PSA was applied to the patient. **Results** No adverse events occurred while PSA was applied to patient. PSA correctly recognized atrial and ventricular heart activity and inhibited in 364/364 (100%) cardiac cycles recorded. PSA correctly caused atrial and/or ventricle capture in 1,621/1,621 (100%) of cardiac cycles recorded. PSA is considered safe and effective.
Conclusion:	Demonstration of substantial equivalence between the PSA™ Series devices (PSA 200™ and PSA 100™), and its predicate device established from clinical and non-clinical performance data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2013

Dr. Markus J. Osypka
Osypka Medical, Inc
7855 Ivanhoe Avenue, Suite 226
La Jolla, California 92037

Re: K123916
Trade Name: PSA™ Series Pacing System Analyzer (PSA 100™ and PSA 200™)
Regulation Number: 21 CFR 870.3600
Regulation Name: External Pacemaker Pulse Generator
Regulatory Class: Class III
Product Code: DTE, DTA
Dated: March 1, 2013
Received: March 4, 2013

Dear Dr. Osypka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123916

Device Names:

OSYPKA MEDICAL	PSA™ Series Pacing System Analyzer PSA 100™ and PSA 200™
CARDIOTRONIC	PSA™ Series Pacing System Analyzer PSA 100™ and PSA 200™

Indications for Use:

This device is indicated for use in stimulation lead system analysis prior or during implantation of an electrical stimulator (pacemaker, pulse generator), for emergency stimulation and for high-rate (burst) stimulation limited to temporary diagnostic and therapeutic application.

Prescription Use (Part 21 CFR 801 Subpart D) X AND / OR Over-The-Counter-Use (Part 21 CFR 807 Subpart C) _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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